## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

NOV 0 1 2006

Application of:

TAKAHARA HAMADA

Ser. No.: 10/786,321

Filed: 2/25/04

SAFETY TEST SUPPORT SYSTEM, METHOD AND PROGRAM

Group Art Unit: 1631

Examiner: Mary Zeman

## RESPONSE TO REQUEST FOR INFORMATION

Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This paper and the accompanying PTO Form-1449 are being submitted in response to the Request for Information dated August 28, 2006. This Response will reference the individual documents referring to the citation letters included on the PTO Form-1449.

A prior art search was performed whereby Documents A and B were discovered. Applicants relied upon Documents C and D to develop the present invention. The names of any products or services that have incorporated subject matter related to the claimed invention are outlined in Document E. A publication which one of the Applicants authored and which describes the disclosed subject matter is provided as Document F. Documents which were used as sources for the description of the prior art include Documents G-I.

> 37 CFR 1.8 CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on 10-30-06 (date).

erri Craine

Document A is related to safety-test evaluation systems. The system disclosed in this reference indicates the data modification log when necessary and includes a data record. The data record consists of one sequence of records that includes the modified study record, which is stored into the modification data file each time the study record is changed. This document fails to disclose "second program storage for storing check programs each for detecting a change in one of the application programs during the system operation; and an inspection conducting means for detecting changes in the application programs by sequentially executing the stored check programs in response to an inspection conducting signal."

Document B relates to program tests. However, multiple test results are kept as a test result log. The system then extracts the difference by comparing the two time separated test results. This document fails to disclose "second program storage for storing check programs each for detecting a change in one of the application programs during the system operation; and an inspection conducting means for detecting changes in the application programs by sequentially executing the stored check programs in response to an inspection conducting signal."

Document C relates to safety-test evaluation systems. This system stores validation procedures and the results. The system runs the stored validation procedure automatically and compares the result with the result of a previously stored result already in the system. This document fails to disclose "second program storage for storing check programs each for detecting a change in one of the application programs during the system operation; and an inspection conducting means for detecting

changes in the application programs by sequentially executing the stored check programs in response to an inspection conducting signal."

Document D relates to safety-test evaluation systems. This system only displays the registered program list and allows a selected program to be operated. This document fails to disclose "second program storage for storing check programs each for detecting a change in one of the application programs during the system operation; and an inspection conducting means for detecting changes in the application programs by sequentially executing the stored check programs in response to an inspection conducting signal."

A specific improvement of claim 1 over the cited art includes "second program storage for storing check programs each for detecting a change in one of the application programs during the system operation; and an inspection conducting means for detecting changes in the application programs by sequentially executing the stored check programs in response to an inspection conducting signal."

A specific improvement of claim 2 over the cited art includes the capability that "if a change that does not affect the system operation is detected in one of the application programs during the system operation, the associated check program ignores the change, and wherein, if a change that affects the system operation is detected in one of the application programs during the system operation, the associated check program regards the change as a change."

A specific improvement of claim 3 over the cited art includes "the inspection conducting means inspects the application programs by: identifying the application program associated with each of the check programs; inputting a

pseudo-signal directly to the identified application program; detecting a response signal responsive to the input pseudo-signal; and comparing the detected response signal with a response signal detected before the inspection."

A specific improvement of claim 4 over the cited art includes that "the pseudo-signal is input without passing through an operation system."

A specific improvement of claim 5 over the cited art includes that "the pseudo-signal is input through an operation system."

Claims 6 and 7 also contain additional differences over the cited art.

Claim 8 is a method claim similar to claim 1 and therefore contains similar improvements over the cited art. Claim 9 is another method claim similar to claim 1 and therefore contains similar improvements over the cited art.

Should any additional information be required, Applicants' undersigned attorney will provide the requested details.

Respectfully submitted,

John S. Mortimer, Reg. No. 30,407

WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. Madison St., Suite 3800 Chicago, IL 60661 (312) 876-1800

Date: 0 ct 30 2006

Comparable to Form PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031 Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

| Substitute for form 1449A/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT |                                   |  |  |             | d to respond to a collection of information unless it displays a valid OMB control  Application Number 10/786,321 |                                |                     |                                      |                 | numbe      |  |  |   |
|--|-----------------------------------|--|--|-------------|---|--------------------------------|---------------------|--------------------------------------|-----------------|------------|--|--|---|
|  |                                   |  |  |             | Filing Date   |                                | _                   | 2/25/04                              |                 |            |  |  |   |
|  |                                   |  |  |             | ٦   | First Named Inventor           |                     |                                      | TAKAHARU HAMADA |            |  |  |   |
|  |                                   |  |  |             |   | Group Art Unit                 |                     |                                      | 1631            |            |  |  |   |
|  | (Use as many sheets as necessary) |  |  |             |   |                                | Examiner Name       |                                      |                 | Mary Zeman |  |  |   |
|  |                                   | Sheet  |  | of          |   |                                | Attorney Docket No. |                                      |                 | /IOR014    |  | <br>030US                                |   |
|  |                                   |  |  | FORE        | EIGN PA   | TEI                            | NT DOCUMENTS        | S                                    |                 |            |  |  |   |
| Examiner<br>Initials'  | Cito                              | For  | Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |             |   |                                |                     | Name                                 | of Pate         | atentee    | Page   | Pages, Columns, Lines,                   |   |
|  | Cite<br>No. <sup>1</sup>          | Country Code                                     |  |             |   | Publication Date<br>MM-DD-YYYY |                     | or<br>Applicant of Cited<br>Document |                 |            | Where Relevant Passages or Relevant Figures Appear | T€                                       |   |
|  | А                                 |  | JP H07-11  | 0325        |   |                                |                     |                                      |                 |            | Englis   | sh Abstract & amined Patent              | - |
|  | В                                 |  | JP H10-27  | 5093        |   |                                |                     |                                      |                 |            | Englis<br>Unexa<br>Public                          | sh Abstract & amined Patent cation       |   |
|  | С                                 |  | JP 2001-11   | 6744        |   |                                |                     |                                      |                 |            | Englis<br>Unexa<br>Public                          | sh Abstract & amined Patent cation       |   |
|  | D                                 |  | JP 2001-18   | 8680        |   | <b></b>                        |                     |                                      |                 |            | Englis<br>Unexa<br>Public                          | sh Abstract &<br>amined Patent<br>cation |   |
|  | $\sqcup$                          |  | <del></del> ,  |             |   |                                |                     |                                      |                 |            |  |  |   |
|  | $\longmapsto$                     |  |  |             |   |                                |                     |                                      |                 |            |  |  |   |
|  |                                   |  |  |             |   |                                |                     |                                      |                 |            |  |  |   |
|  | $\vdash$                          | <del>                                     </del> |  |             |   |                                |                     |                                      |                 |            |  |  |   |
|  | $\vdash$                          |  |  |             |   |                                |                     |                                      |                 |            |  |  |   |
|  | <del>  </del>                     |  |  |             |   |                                |                     | <del>.</del>                         |                 |            |  |  |   |
|  |                                   |  |  |             |   |                                |                     |                                      |                 |            |  |  |   |
|  | <del></del>                       |  |  |             | -+  |                                |                     | _                                    |                 |            | <del></del>  |  |   |
|  |                                   |  |  |             |   |                                |                     | <del></del>                          |                 |            |  |  |   |
|  |                                   |  |  | <del></del> |   |                                |                     |                                      |                 |            |  |  |   |
|  |                                   | <u></u>  |  |             |   |                                |                     |                                      |                 | -          |  |  |   |
|  |                                   |  |  |             |   |                                |                     |                                      |                 | $\dashv$   |  |  |   |
| Examiner Si  | ignature                          |  |  |             |   |                                | 1                   |                                      | Date C          | Conside    | red  |  |   |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standards ST.16, if possible. <sup>6</sup> Applicant is to place a checkmark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) and application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450. 1450.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.

Comparable to Form PTO/SB/08A (08-03 Approved for use through 0731/2006 OMB 0651-0031 Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| Substitute for form 1449A/PTO |              |         |   | Application Number   | 10/786,321         |  |  |  |
|-------------------------------|--------------|---------|---|----------------------|--------------------|--|--|--|
|                               |              |         |   | Filing Date          | 2/25/04            |  |  |  |
| INFORMATION                   |              |         |   | First Named Inventor | TAKAHARU HAMADA    |  |  |  |
| STATEMENT E                   | BY APPL      | LICANT  |   | Group Art Unit       | 1631<br>Mary Zeman |  |  |  |
| (Use as many she              | eets as nece | essary) |   | Examiner Name        |                    |  |  |  |
| Sheet                         | 2            | of      | 2 | Attorney Docket No.  | MUR-01460P00030US  |  |  |  |

|                       |   | OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS   |    |  |  |  |  |  |
|-----------------------|---|---|----|--|--|--|--|--|
| Examiner<br>Initials* | Cite<br>No.1  | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² |  |  |  |  |  |
|                       | E   | TOX LAUNCHER - Advertisement/Information Sheet  |    |  |  |  |  |  |
|                       | F Functions and Developments of TOX-LAUNCHER - Author: Takaharu Hamada - Updated February 2005  |   |    |  |  |  |  |  |
|                       | G   | 21 CFR Part 58  |    |  |  |  |  |  |
|                       | H Guidance for Industry - Part 11, Electronic Records; Electronic Signatures - Scope and Application - August 2003 Pharmaceutical CGMPs |   |    |  |  |  |  |  |
|                       | 1   | Part 11 - Final Rule and Discussion   | -  |  |  |  |  |  |
|                       |   |   |    |  |  |  |  |  |
|                       |   |   |    |  |  |  |  |  |
|                       |   |   |    |  |  |  |  |  |
|                       |   |   |    |  |  |  |  |  |
|                       |   |   |    |  |  |  |  |  |
|                       |   |   |    |  |  |  |  |  |
| Examiner Signature    |   | Date Considered   |    |  |  |  |  |  |

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) and application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450.